

09/808,002
Response to Office Action of June 1, 2006
Via facsimile 571-273-8300
Date of Deposit: August 1, 2006

Attorney Docket Number US 010387

Remarks

Claims 1-2, 4-8, 15 and 23 are herein amended. Support for amendment of claim 1 is found in the specification as filed, ¶ [0015], on page 5, and in claim 3 as originally filed. Support for amendment of claims 2-7 is found in the specification as filed, ¶ [0015], on page 5. Support for amendment of claim 8 is found in claims 8 and 10 as originally filed. Support for amendment of claim 15 is found in claims 15 and 17 as originally filed. Support for amendment of claim 23 is found in this claim as originally filed.

Claims 3, 10 and 17 are herein canceled. Claims 1-2, 4-9, 11-16 and 18-23 are pending in the application. No new matter has been added, and no new material presented that would necessitate an additional search on the part of the Examiner.

Applicants note with appreciation that previous rejection of claim 22 under 35 U.S.C. §112 ¶2 has been withdrawn.

Claim objections

The Office Action on page 2, ¶2 objects to claim 23 as being in improper form because it is a multiple dependent claim. Applicants assert that claim 23, which cites to claim 15 and therefore depends only on claim 15, is not a multiple dependent claim. Applicants assert that claim 23 is in proper form, and that this objection can be withdrawn. Alternatively, Applicants respectfully request further information.

Issues under 35 U.S.C. §112 ¶2

The Office Action on page 2, ¶5 rejects claims 1-7 and 23 under 35 U.S.C. §112 ¶2.

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Claim 1 as here amended is directed to a report generator machine with computer instructions embodied on a computer readable medium downloaded for processing by the machine.

Claim 23 as here amended is directed to a computer-readable medium including a set of computer instructions stored on the computer-readable medium, wherein the computer instructions are downloaded for processing by a general purpose computer to carry out the method of claim 15.

Applicants assert that claims 1 and 23 as here amended are proper according to 35 U.S.C. §112 ¶2.

Claims 2-7 depend directly on claim 1 and therefore incorporate the subject matter of this claim as here amended, therefore these claims also conform to 35 U.S.C. §112 ¶2. Applicants respectfully request that rejection of claims 1-7 and 23 be withdrawn.

Claims as amended comply with 35 U.S.C. §101

The Office Action on page 3, ¶6 rejects claims 1-7 and 23 under 35 U.S.C. §101 as directed to non-statutory subject matter.

Claims 1-7 as here amended are directed to a machine. Claim 23 as here amended is directed to a computer readable medium including a set of computer instructions stored on the computer-readable medium, wherein the computer instructions are downloaded for processing by a computer to carry out the method of claim 15.

Claims 2-7 depend directly on claim 1 as here amended and therefore incorporate the subject matter of this claim as here amended. Applicants assert that claims 1-7 and 23 as

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here amended satisfy the requirements of 35 U.S.C. §101, and respectfully request that this rejection be withdrawn.

Claims are not obvious

Whether an invention would have been obvious under 35 U.S.C. §103(a) is a legal conclusion based on underlying findings of fact. *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

The *Manual of Patent Examining Procedure* states: "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." [emphases added] *Manual of Patent Examining Procedure* §2142 (8th Ed. Rev.2, May 2, 2004); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully traverse the rejection, and show that the facts of the case and the relevant case law indicate that the invention would not have been obvious to one of ordinary skill in the art, at the time the application was filed, for the following reasons.

To establish a *prima facie* case for obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *Manual of Patent Examining Procedure*, §2143.03, p. 108 (8th Ed. Rev.2, May 2, 2004); *In re Royka*, 490 F.2d 981, 180

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USPQ 580 (CCPA 1974). We show below that none of the references alone or in any combination teach or suggest all of elements of Applicants' claims.

Prior to analyzing the art cited in the Office Action, Applicants believe that a brief description of the subject matter of independent claim 1 as here amended and independent claims 8 and 15 would be of use to the Examiner.

Claim 1 as here amended is directed to a report generator machine for automatically and electronically generating a computer-readable medical report. The machine includes means for providing at least one predetermined field arranged within the medical report that includes data representative of a medically relevant characteristic. The characteristic is replaced with a calculation value derived from one or more measurements. The machine also includes means for automatically inserting data representative of the medically relevant characteristic into the predetermined field upon report generation. The means for providing and the means for inserting comprise computer instructions embodied in a computer readable medium downloaded for processing by the machine that is a general purpose computer, a personal computer, or a specialized report generator.

Claim 8 as here amended is directed to a system for electronically generating a medical report. The system includes a report generator for generating an electronic medical report, which has at least one predetermined field to hold data representative of medical characteristic. The report generator includes an interface for receiving data input. Upon automatic generation of the medical report, a measured value defining a medical characteristic is inserted into the field so that the generated medical report is included with the medical characteristic, and the medical characteristic is replaced with a calculation value

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derived from one or more measurements.

Claim 15 as here amended is directed to a method of electronically generating a medical report including a plurality of fields representative of a plurality of medical conditions, with steps of electronically selecting a medical condition for inclusion within the medical report, automatically inserting a measurement corresponding to the selected medical condition when the medical report is generated so that the measurement replaces the field, and replacing the measurement value with a calculation derived from one or more measurements.

The Office Action on page 4, ¶8 rejects claims 1-2, 4-9, 11-16 and 18-23 under 35 U.S.C. §103(a) in view of Applicants' background of the invention (pages 1-2 of Applicants' specification) in combination with Coli et al. (U.S. patent number 6,018,713, issued January 25, 2000).

Applicants' background of the invention

The Office Action on page 6 alleges that Applicants' background of the invention teaches that it is known to automatically insert a measurement corresponding to the selected medical condition when the medical report is generated.

Applicants respectfully disagree, and assert that Applicants' background of the invention clearly points out substantial limitations of the related prior art, a need for which claims 1, 8 and 15 are addressed. Applicants' background states:

Another known report generation system feature enables the entry of measurement values into the report generation system such that various measurements pertaining to a patient's medical condition may be automatically inserted into a report. The measurements are usually included in a separate section of the report. The measurements may be typed in or may be derived by the report generation system from other user input, such as

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indicating points on a medical image between which distance or other metrics may be calculated.

In a medical report of the related art, it is possible to enter in a free text diagnosis that may contain a measurement value. The free text can then be manually modified. However, re-performing an automatically calculated measurement does not automatically change the free text portion of the report. Thus, measurements changed in a measurement section of the report may be inconsistent with the free text in the interpretation section of the report. In addition, the process of free text entry is error prone and may result in an incorrect measurement value being transcribed. [See Applicants' specification as filed, ¶ [0006] and [0007]; emphases added]

Applicants' background addresses the substantial problems in the prior art and lack of teaching in that prior art, evidenced by the quotations above. Applicants' claims 1, 8 and 15 are directed to a report generator machine, a system and a method generating a computer-readable medical report. At least one predetermined field is provided within the medical report, which includes data representative of a medically relevant characteristic, where the characteristic is replaced with a calculation value derived from one or more measurements. Data representative of the medically relevant characteristic is automatically inserted into the at least one predetermined field upon report generation.

The quotations above clearly show that Applicants at the time the application was filed clearly asserted that the prior art fails to teach or suggest a predetermined field provided within a medical report, as is the subject matter of Applicants' claims 1, 8 and 15 as here amended.

Further, the prior art cited in Applicants' background fails to teach or suggest a medical characteristic replaced with a calculation value derived from one or more measurements, as is the subject matter of Applicants' claims 1, 8 and 15 as here amended.

The prior art also fails to teach or suggest that data representative of a medically

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relevant characteristic is automatically inserted into a predetermined field upon report generation, as is the subject matter of Applicants' claims 1, 8 and 15 as here amended.

Coli et al., U.S. patent number 6,018,713, issued January 25, 2000

Coli et al. taken as a whole shows systems for ordering medical tests on-line in a health care network, i.e., a network that would be used by remotely located medical personnel, and recording and reporting the test results, and collecting and statistically analyzing test results. See Coli et al., column 1, lines 9-14. Coli shows providing a test ordering module for organizing tests in clinical groupings. Ibid, column 3, lines 1-5. Coli also shows providing a system for ordering tests and reporting results where other data, such as a clinical description of the test or demographic information, may be attached to the test result output. Ibid, column 3, lines 6-8.

Coli et al. fails to teach or suggest a report generator machine for automatically and electronically generating a computer-readable medical report that has means for automatically inserting data in a predetermined field, as is the subject matter of Applicants' claim 1 as here amended. Coli et al. shows only a network for ordering tests and reporting results of these tests. See Coli et al., column 1, lines 9-14. Coli et al. thus fails to teach or suggest any system or method for automatically inserting data of a medically relevant characteristic into a predetermined field upon generating a medical report, as is the subject matter of claims 1, 8 and 15 as here amended.

Further, Coli fails to teach or suggest a medical characteristic replaced with a calculation value derived from one or more measurements, as is the subject matter of Applicants' claims 1, 8 and 15 as here amended.

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In contrast to the prior art including Coli et al., Applicants' claims 1, 8 and 15 as here amended are directed to means for providing at least one predetermined field in a medical report that includes data representative of a medically relevant characteristic, wherein the medical characteristic is replaced with a calculation value derived from one or more measurements, and means for automatically inserting data representative of a medically relevant characteristic into at least one predetermined field upon report generation.

Claim 1 is directed to a report generator machine with means for providing at least one predetermined field arranged within a medical report that includes data representative of a medically relevant characteristic, wherein the characteristic is replaced with a calculation value derived from one or more measurements, and means for automatically inserting data representative of a medically relevant characteristic into at least one predetermined field upon report generation.

Claim 1 as here amended is not obvious because none of the cited references, alone or in combination, teach or suggest a report generator machine for automatically and electronically generating a computer-readable medical report that has means for automatically inserting data in a predetermined field. Further, the cited reference fail to teach or suggest a medically relevant characteristic replaced with a calculation value derived from one or more measurements. Claims 2 and 4-7 depend from claim 1 and therefore include the subject matter of claim 1 and contain additional subject matter.

With respect to claims 1-2 and 4-7, none of the cited primary references show a means for automatically inserting data representative of a medically relevant characteristic into at least one predetermined field upon report generation, or that a medically relevant

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characteristic in a predetermined field is replaced with a calculation value derived from one or more measurements.

Therefore, according to the legal criteria discussed above, analysis of the underlying facts of the present pending claims show that the prior art does not teach or suggest all the subject matter of the claims of the present invention. Therefore, the Office Action fails to establish a *prima facie* case that claim 1 is obvious. Claims 2-7 that depend directly from claim 1 and incorporate the subject matter of claim 1 and contain additional subject matter also are not obvious in light of the cited references.

Claim 8 as here amended is directed to subject matter including that upon automatic generation of the medical report, a measured value defining a medical characteristic is inserted into the field so that the generated medical report is included with the medical characteristic, and the medical characteristic is replaced with a calculation value derived from one or more measurements.

Claim 8 is not obvious because none of the cited references, alone or in combination, teach or suggest a system for electronically generating a medical report where upon automatic generation of the medical report, a measured value defining a medical characteristic is inserted into the field so that the generated medical report is included with the medical characteristic, or teach or suggest that the medical characteristic is replaced with a calculation value derived from one or more measurements.

Claims 9, 11-14 and 22 depend from claim 8 and therefore include the subject matter of claim 8 of a means for automatically inserting data. None of the cited primary references show the element of claim 8 of a system for electronically generating a medical report where

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a measured value is inserted into a predetermined field upon automatic generation of the medical report.

Therefore, according to the legal criteria discussed above, analysis of the underlying facts of the present pending claims show that the prior art does not teach or suggest all the subject matter of the claims of the present invention. Therefore, the Office Action fails to establish a *prima facie* case that claim 8 of the present invention is obvious. Claims 9, 11-14 and 22 that depend directly from claim 8 and incorporate the subject matter of claim 8 and contain additional subject matter also are not obvious in light of the cited references.

Claim 15 as here amended is directed to a method where a measurement corresponding to the selected medical condition is automatically inserted when the medical report is generated whereby the measurement replaces the field, and a medical characteristic is replaced with a calculation value derived from one or more measurements.

Claim 15 is not obvious because none of the cited references, alone or in combination, teach or suggest a method of electronically generating a medical report that includes automatically inserting a measurement corresponding to a selected medical condition when the medical report is generated so that the measurement replaces the field. The cited references also fail to teach or suggest replacing a medical characteristic with a calculation value derived from one or more measurements. Claims 16, 18-21 and 23 depend from claim 15 and therefore include the subject matter of this claim and additional subject matter.

With respect to claims 16, 18-21 and 23, none of the cited references show a method of electronically generating a medical report that includes automatically inserting a

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measurement corresponding to a selected medical condition upon generating the report wherein the characteristic is replaced with a calculation value derived from one or more measurements, as is the subject matter of claim 15.

Therefore, according to the legal criteria discussed above, analysis of the underlying facts of the present pending claims show that the prior art does not teach or suggest all the subject matter of the claims of the present invention. Therefore, the Office Action fails to establish a *prima facie* case that claim 15 of the present invention is obvious. Claims 16, 18-21 and 23 that depend directly from claim 15 and incorporate the subject matter of claim 15 and contain additional subject matter also are not obvious in light of the cited references.

As Coli et al. fails to cure the defects of Applicants' background with respect to claims 1, 8 and 15, therefore claims 1-2, 4-9, 11-16 and 18-23 are not obvious in view of Applicants' own background and the cited reference, alone or in combination. Applicants respectfully request that rejection of claims 1-2, 4-9, 11-16 and 18-23 be withdrawn.

The Office Action on page 5, ¶9 rejects claims 3, 10 and 17 under 35 U.S.C. §103(a) in view of Applicants' background of the invention (pages 1-2 of Applicants' specification) in view of Coli et al. (U.S. patent number 6,018,713, issued January 25, 2000) and further in view of Stoodley (U.S. patent number 6,611,846, issued August 26, 2003).

Claims 3, 10 and 17 are herein canceled therefore this rejection is moot. Applicants respectfully request that this rejection be withdrawn.

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Legal analysis

Lack of motivation to combine cited references

To establish obviousness based on a combination of the elements disclosed in the prior art in the absence of any hindsight, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *Id.* The teaching or suggestion, not merely to make the claimed combination, but also of a reasonable expectation of success, must both be found in the prior art, and not based on applicant's disclosure. *In re Vaack*, 947 F.2d 488; 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Applicants show below that none of the prior art references, taken as a whole at the time the application was filed, would have explicitly motivated or suggested combining these references, let alone having motivated the invention of the claims, let alone providing an expectation of success.

Applicants' background, the more recent of the primary references, does not cite Coli et al., the earlier reference, because this reference, describing a healthcare network, is not material to the claims. There is no motivation for one of ordinary skill in the art of automatic report generation making any combination with Coli et al., nor is there any suggestion that such a combination would have been successful. For these reasons also, the combination of these references fails to teach or suggest the present claims.

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Therefore, making the combination is using Applicant's own specification as a blueprint to reconstruct the invention, which is impermissible hindsight, viz., extracting merely an element or word from each reference, to attempt to reconstruct Applicant's claims when none of the references explicitly or implicitly teaches or suggests such a combination, let alone teaches or suggests a reasonable expectation of success.

The knowledge generally available to one of ordinary skill in the art would not have rendered the claims of the present invention obvious

As a preliminary matter, Applicants acknowledge that in certain cases, courts describe motivation to combine references in the knowledge of one of ordinary skill in the art, however these cases limited such motivation to well-described factual circumstances. A series of decisions described below explain when the knowledge of one of ordinary skill in the art provides sufficient motivation to combine references for an obviousness rejection, and define the metes and bounds of when the knowledge of one of ordinary skill in the art sufficiently provides the motivation to combine references. Thus, a court points out, "[a] statement that modifications of the prior art would have been within the ordinary skill of the art at the time the claimed invention was made, because the references relied upon teach that all aspects of the claimed invention were individually known in the art, is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references." [emphases added] *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab*, 217 F.3d 1365, 1371; 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000).

Courts generally agree that whether an Examiner relies on an express or an implicit showing, particular findings related thereto must be provided. [emphasis added] See *In re*

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Kotzab, 217 F.3d at 1370. Broad conclusory statements standing alone are not "evidence" *Id.* A legal determination of obviousness is based on facts underlying the claims, and failure to reference or analyze these facts, or to address the underlying relevant case law, is merely conclusory.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so, found either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art. The legal criteria to determine the extent to which such knowledge is in the general art, rather than in a specification, has been extensively addressed by recent court decisions analyzed below.

In *In re Kotzab*, claims were directed to an injection molding method for forming plastic articles involving the use of a single sensor to control a plurality of flow control valves. *In re Kotzab* 217 F.3d at 1367. The Examiner rejected the claims because the primary reference taught that one system constructed and operated according to the invention may be used to control a number of valves. [emphasis added] *Id.*

The court disagreed, stating that there was not substantial evidence to show that "one system" is the same as "one sensor". The court explained that the Examiner and the Board of Patent Appeals and Interferences fell into the hindsight trap because a single sensor as opposed to multiple sensors is a technologically simple concept. [emphasis added] *Id.* at 1371. The court concluded however, that "there was no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have

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motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed." [emphases added] *Id.*

Similarly, the court disagreed with the reasoning of the Examiner in the case *In re Fine* 837 F.2d 1071, 1072-1073 (Fed. Cir. 1988), in which claims had been rejected as obvious. The court pointed out that neither the Examiner nor the Board of Patent Appeals and Interferences offered any support or explanation for the conclusion that the substitution of one type of detector for another would have been within the skill of the art. *Id.* at 1074; emphasis added. The court explained that neither reference, alone or in combination, suggested the claimed invention, and the Board erred in affirming the Examiner's conclusion that it would have been obvious to substitute an element in one cited reference for a different element in the other cited reference. *Id.* at 1075. The court further explained that whether a particular combination might be "obvious to try" is not a legitimate test of patentability. *Id.*

The claims in *In re Jones* directed to a salt were rejected as obvious, the Examiner pointing out that known forms of the salt in a cited reference had similar utility and one of ordinary skill in the art would appreciate that the salt group has significance with respect to imparting activity to such compounds. *In re Jones*, 958 F.2d 347, 348-351 (Fed Cir. 1992). The Solicitor contended that one skilled in the art would have been motivated to expect the salt to have herbicidal activity. *Id.*

The court disagreed, stating there must be some suggestion or teaching to combine the disclosures of two or more prior art references in order to establish prima facie obviousness. *Id.* The suggestion or teaching must be found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *Id.*

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The court further determined that there was no such suggestion in one of the cited references. *Id.* The court stated that conspicuously missing from the record was any evidence, other than the speculation that one of ordinary skill in the herbicidal art would have been motivated to make the modifications necessary to arrive at the claimed salt. *Id.*

Two recent cases deal with the metes and bounds of application of the knowledge of one of ordinary skill in the art as a proper motivation for combining references, and are described herein because the facts of these cases can be distinguished from the facts of the present application.

In *Ruiz v. A.B. Chance Company*, 357 F.3d 1270; 69 U.S.P.Q.2d 1686 (Fed. Cir. 2004), the two prior art references both addressed precisely the same problem: the use of screw anchors to underpin existing structural foundations. The court explained that proper motivation to combine two references was found in the nature of the problem to be solved because the two cited references in this case addressed precisely the same problem of underpinning existing structural foundations. [emphases added] *Id.* at 1276. The court further stated that because the prior art references address the narrow mechanical problem of underpinning existing building foundations, a person seeking to solve that exact same problem would consult the references and apply their teachings together. [emphasis added] *Id.*

Ruiz provides a very narrow scenario for when the nature of the problem can provide the implicit motivation to combine references, requiring the prior art references cited to address precisely the same problem. In contradistinction to *Ruiz*, in the present application none of the prior art references addresses precisely the same problem. Further, none of these

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references teach or suggest how to combine any of the other references to arrive at the subject matter of the claims as here amended. Therefore, the narrow holding of *Ruiz* is inapposite to the present case.

A second recent case, *National Steel Car, Ltd. v. Canadian Pacific Railway, Ltd.*, 357 F.3d 1319, 69 U.S.P.Q.2d 1641 (Fed. Cir. 2004), also addresses the issue of when motivation to combine references can be considered proper. In *National Steel Car*, the claims at issue were directed to a railcar with a "drop deck". *Id.* at 1322. In *National Steel Car*, the court determined that the motivation to combine the two prior art references was implicit in the knowledge of one of ordinary skill in the art in that case, because both of the references independently arrived at the "drop deck" railcar design. [emphasis added] See *Id.* at 1337-1340. Since two different inventors in the field independently arrived at the claimed invention, the court decided that the motivation to combine the two cited prior art references was implicit in the knowledge of one of ordinary skill in the art. See *Id.*

The facts of that case are readily distinguishable from the facts of the present application. Unlike in *National Steel Car*, in the present claims none of the references teaches or suggests all of the elements of Applicants' claimed subject matter. Additionally, none of the prior art references suggests the combination of the references cited by the Office Action. Finally, the combination of all of the cited references fails to teach or suggest every element of independent claims 1, 8 and 15 as here amended.

In the present case, Applicants' background of the invention shows report generation systems that enables the entry of measurement values into the report generation system, where the measurements are usually included in a separate section of the report. See

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Applicant's specification as filed, ¶ [0006]. Applicants' background however clearly points out that the prior art fails to teach or suggest a predetermined field provided within a medical report, or teach or suggest a medical characteristic replaced with a calculation value derived from one or more measurements, as is the subject matter of Applicants' claims 1, 8 and 15 as here amended.

Coli et al. shows systems for ordering medical tests on-line in a health care network, i.e., a network that would be used by remotely located medical personnel, and recording and reporting the test results, and collecting and statistically analyzing test results. See Coli et al., column 1, lines 9-14.

These references neither teach nor suggest how to modify any of the technology of any of the other cited references, to combine with the other references, let alone teach or suggest the subject matter of the claims of the present application. Therefore, clearly, the narrow holdings of *Ruiz* and *National Steel Car* are inapposite to the present claims.

Thus, analysis of the facts of the present claims and the facts of the cited prior art, viz., lack of teachings of all of the subject matter of the claims as here amended, clearly distinguish the present case from both *Ruiz* and *National Steel Car*, and demonstrate that the motivation to combine the references cited by the Office Action was not in the knowledge generally available to one of ordinary skill in the art. Rather, the present specification and claims have been used as a blueprint to pick and choose references to reconstruct the invention, which is impermissible hindsight.

For any of the above reasons, Applicants assert that claims 1-2, 4-9, 11-16 and 18-23 are not obvious, and respectfully request that the rejection be withdrawn.

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Summary

On the basis of the foregoing reasons, Applicants respectfully submit that the pending claims are in condition for allowance, which is respectfully requested.

If there are any questions regarding these remarks, the Examiners are invited and encouraged to contact Applicants' representative at the telephone number provided.

Respectfully submitted,

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